

the scientific peer review panel are reported in the June 20, 2002 report entitled Interim Consensus Report of the HARS Scientific Peer Review. Phase 1: Human Health Evaluation (USEPA, 2002a). EPA intends to resume Remediation Material Workgroup (RMW) meetings with the focus on the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use at the HARS as Remediation Material, before responding to the peer reviewers' consensus report and finalizing the human health and ecological effects testing evaluation framework (TEF).

One of the central consensus opinions of the 2002 scientific peer review panel is that improvement of estimates of key exposure parameters requires that site-specific studies be conducted to obtain updated or better information. The USACE and EPA have developed several scopes of work for studies to obtain this information. It is clear, however, that many of these necessary studies will require substantial time to complete. The interim PCB tissue criterion would ensure that material that is placed at the HARS attains a level of protection consistent with the current best estimates of exposure and with the remedial intent of the HARS.

The PCB criterion will remain in effect until after EPA and the USACE complete their review of the 2002 scientific peer review comments on the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use at the HARS as Remediation Material for human health effects, conduct and respond to the comments on the future scientific peer review on the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use at the HARS as Remediation Material for ecological effects, and revise, as necessary, the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use as Remediation Material at the HARS for all contaminants of concern in accordance with the September 27, 2000 MOA between EPA and the USACE. When the above steps are completed, any further changes to the HARS testing evaluation process used to evaluate PCBs, or other contaminants of concern, will be the subject of further rulemaking, as necessary. EPA estimates that it will take four to five years to fully complete this process, including additional rulemaking, as necessary.

Exposure Assumptions Are Too Conservative

A frequent observation made in the negative comments on the proposed rule is that the site-specific exposure assumptions used by EPA in calculating the 113 ppb HARS-specific PCB worm tissue criterion are "overly conservative" or "unrealistic." EPA rejects this assertion. The 113 ppb HARS-specific PCB worm tissue criterion is designed to be appropriately conservative to protect human health and the marine environment. The value was calculated using a non-cancer Hazard Quotient of 1, the level recommended by EPA Superfund guidance for remediation of sites with hazardous substance contamination; and a cancer risk factor of 10^{-4} , the minimum level recommended by EPA Superfund guidance.

Where EPA was conservative in calculating the PCB criterion, this conservative approach was appropriate given the relative paucity of data from which to derive alternative, site-specific exposure figures. However, the conservatism of individual exposure assumptions made in the calculation is balanced by EPA's use of a less conservative cancer risk level of 1×10^{-4} . Had EPA chosen a more protective cancer risk level of 1×10^{-5} or 1×10^{-6} , as is typical when selecting goals for site remediation, the calculated HARS-specific PCB worm tissue criterion would have been one or two orders of magnitude lower. Thus, EPA believes that the use of what some comments contend is an unrealistically conservative set of exposure assumptions (selected because of the absence of data on which to base arguably more realistic assumptions) is more than offset by EPA's use of a cancer risk level which is at the very low end of what is considered acceptable under EPA's other hazardous site remediation programs. If reliable, site-specific exposure data were available, EPA would use them in its calculations. In finalizing the review of the HARS testing evaluation process, EPA will also evaluate the use of a cancer risk level that is more protective and more consistent with what is typically used in Superfund site remediation. If EPA were to select a more protective cancer risk level, even with different exposure data, the net result might well be a calculated PCB value no higher than, and almost certainly lower than, 113 ppb.

The comments that criticized EPA's conservative exposure assumptions also failed to note the ultimate intent of the proposed rule, which is to further the

remediation of the HARS. The need for and intent of such remediation was clearly established in the HARS designation in 1997 (62 FR 46142).

Implementation of the 113 ppb HARS-Specific PCB Worm Tissue Criterion Will Have Significant Negative Economic Consequences

Some comments have made dire predictions about economic dislocations if EPA proceeds with the proposed promulgation of the 113 ppb HARS-specific PCB worm tissue criterion. EPA does not believe that this will be a likely outcome. On the contrary, dredging activity, and placement of dredged material at the HARS, has continued apace in the more than two years since the September 2000 MOA, when EPA and USACE first started using the PCB value of 113 ppb. Undoubtedly, some dredgers who would wish to use the HARS will be unable to do so because their material does not satisfy the 113 ppb criterion; and it may cost more for these individual dredgers to dispose of the material elsewhere. However, EPA disagrees that widespread, adverse economic consequences are to be expected from this rulemaking. Specifically, there has been more dredged material placed at the HARS since the 113 ppb PCB value was announced under the September 2000 MOA (approximately 11 million cubic yards, based on scow volume, of maintenance and deepening dredged material), than was placed in previous years (approximately 4 million cubic yards, based on scow volume, of maintenance and deepening) (USACE, 2002). A PCB criterion of 113 ppb would render only approximately 300,000 cubic yards of maintenance dredged material from 3 past projects, since the September 2000 MOA (U.S. Gypsum, Port Imperial, and a portion of Naval Weapons Station Earle), unsuitable for placement at the HARS at an estimated cost of \$14.1 million. A PCB criterion of 113 ppb would render approximately 1.2 million cubic yards (including the 300,000 mentioned earlier) of maintenance dredged material from 8 past projects (including the three discussed above) since the HARS was designated (Buttermilk Channel, Raritan River, Raritan Cutoff, Refined Sugars [now American Sugars], and Castle Astoria) unsuitable for placement at the HARS, which represents an average of 240,000 cubic yards per year (over a 5 year period). EPA estimated a worst case scenario of 1.33 million cubic yards in any given year would be unsuitable for the HARS based upon today's rule, at a cost of \$62.5 million. See response to comment 7-2 in the Response to